LDLWIYHTQGYFPDWQNYTPGPGVRYPLTFGWCYKLVPVEPDKVEEANKGENTSLLH PVSLHGMDDPEREVLEWRFDSRLAFHHVARELHPEYFKNC;

- (b) reagents for detecting the hybrids; and
- (c) a biological reference sample lacking nucleic acid recognized by said nucleic acid probe composition.

46. (NEW) The kit according to claim 45, wherein said probe is labeled with a label selected from the group consisting of a radioactive label, an enzymatic label, and a fluorescent label. --

## **REMARKS**

Reconsideration of this application is respectfully requested.

Claims 11-18 have been canceled. Claims 35-46 are new and are derived from canceled claims 11-18. New claims 35-46 are fully supported by the specification, for example at page 1, lines 7-13; page 12, line 29, through page 15, line 14; page 16, lines 10-13; page 17, lines 3-11; and Figures 2, 3, 8, 9, 11, 12, 23, 25, and 26. No new matter enters by amendment.

As requested by the Examiner, applicants submit herewith a copy of the original claims which were involved in Interference No. 102,822.

Claims 17 and 18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 08/308,218 in view of White et al. (U.S. Patent No. 4,677,054). Claims 15 and 16 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-22 of copending Application No. 08/202,239 in view of White et al. (U.S. Patent No.

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LL®

4,677,054). Since these are provisional rejections, applicants request that the rejections be held in abeyance until allowance of the pending claims.

Claims 11, 13, 15, and 17 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Chang et al. (U.S. Patent No. 6,001,977). The Examiner alleges that Chang discloses *in vitro* diagnostic methods for detecting the presence or absence of HIV-1 virus.

Applicants' new claims 35-46 recite methods and kits using probes comprising HIV-1 ORF-1, ORF-4, and ORF-R sequences. The proteins encoded by ORF-1, ORF-4, and ORF-R are now known as the Vpr, Vpu, and Nef proteins of HIV-1.

In the attached Tables 1, 3, and 5, applicants provide a comparison of DNA sequences from ORF-R (Nef), ORF-1 (Vpr), and ORF-4 (Vpu) from LAV with the sequences of these regions from the Chang patent (BH10, BH5, and BH8). The sequences of Chang contain stop codons in the ORF-1 and ORF-R reading frames. In Table 1 and Table 3, applicants have highlighted the in-frame stop codons present in the ORF-R (Nef) and ORF-1 (Vpr) reading frames of the BH10 and BH8 sequences of Chang. As a result of these stop codons, the sequences of Chang do not encode full-length HIV-1 Vpr and Nef proteins as claimed by applicants. Therefore, Chang cannot anticipate the methods and kits of new claims 35-46. Accordingly, applicants respectfully request withdrawal of the rejection.

In the attached Tables 2, 4, and 6, applicants have also provided a comparison of DNA sequences from ORF-R (Nef), ORF-1 (Vpr), and ORF-4 (Vpu) from LAV with the sequences of these regions from ARV in U.S. Patent No. 5,156,949 to Luciw et al. The sequence of Luciw contains a stop codon in the ORF-4 (Vpu) reading frame. In

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

Table 6, applicants have highlighted the in-frame stop codon present in the ORF-4 (Vpu) reading frame of the ARV sequence of Luciw. As a result of this stop codon, the sequence of Luciw does not encode full-length HIV-1 Vpu protein as claimed by applicants. Accordingly, Luciw also cannot anticipate the methods and kits of new claims 35-46.

Claims 11-18 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over by Chang et al. (U.S. Patent No. 6,001,977) in view of White et al. (U.S. Patent No. 4,677,054). The Examiner alleges that it would have been *prima facie* obvious to combine the method of White with the method of Chang.

Applicants' new claims 35-46 recite methods and kits using probes comprising HIV-1 ORF-1 (Vpr), ORF-4 (Vpu), and ORF-R (Nef) sequences. The sequences of Chang do not encode full-length HIV-1 Vpr and Nef proteins as claimed by applicants. Chang did not even identify open reading frames encoding these proteins. White does not remedy these deficiencies. Consequently, Chang and White cannot make applicants' claimed invention obvious. Accordingly, applicants respectfully request withdrawal of the rejection.

Furthermore, the sequence of Luciw does not encode full-length HIV-1 Vpu protein as claimed by applicants. Luciw did not even identify an open reading frame encoding this protein. Consequently, Luciw also cannot make applicants' claimed invention obvious.

Applicants respectfully submit that this application is now in condition for allowance. In the event that the Examiner disagrees, he is invited to call the

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 3, 2002

By: Salvatore J. Arribo

Registration No. 46,063 Telephone: 202-408-4160 Facsimile: 202-408-4400

E-mail: arrigos@finnegan.com

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP



gacagggcttggaaaggattttgctataagatgggtggcaagtggtcaaaaagtagtgtggttggatggccta gacagggcttggaaaggattttgctataagatgggtggcaagtggtcaaaaagtagtgtggttggatggcctg gacagggcttggaaaggattttgctataagatgggtggcaagtggtcaaaaagtagtgtggttggatggcctg	ctgta	LAV BH10 BH8
agggaaagaatgagacgagctgagccagcagcagatggggtgggagcagcatctcgagacctggaaaaacatgaggaaagaatgagacgagctgagccagcagcagcagggggggg	gagca	LAV BH10 BH8
atcacaagtagcaatacagcagctaccaatgctgcttgtgcctggctagaagcacaagaggaggaggaggtggatcacaagtagcacacagcagctaacaatgctgattgtgcctggctagaagcacaagaggaggaggaggtggatcacaagtagcaatacagcagctaccaatgccgattgtgcttggctagaagcacaagaggaggaggaggaggtgg	gtttt	LAV BH10 BH8
ccagtcacacctcaggtacctttaagaccaatgacttacaaggcagctgtagatcttagccactttttaaaag ccagtcacacctcaggtacctttaagaccaatgacttacaaggcagctgtagatcttagccactttttaaaaag ccagtcacacctcaggtacctttaagaccaatgacttacaaggcagctgtagatcttagccactttttaaaaag	aaaag	LAV BH10 BH8
gggggactggaagggctaattcactcccaacgaagacaagatatccttgatctgtggatctaccacacaca	gctac	LAV BH10 BH8
ttccctgattggcagaactacacacagggccaggggtcagatatccactgacctttggatggtgctacaagc ttccctgat <b>tag</b> cagaactacacaccagggccagggatcagatatccactgacctttggatggtgctacaagc ttccctgattggcagaactacacaccagggccaggagtcagatatccactgacctttggatggtgctacaagc	tagta	LAV BH10 BH8
ccagttgagccagataaggtagaagaggccaataaaggagagaacaccagcttgttacaccctgtgagcctgc ccagttgagccagagaagttagaagaagccaacaaaggagagaacaccagcttgttacaccctgtgagcctgc ccagttgagccagagaag <b>taa</b> gaagaagccaataaaggagagaacaccagcttgttacaccctgtgagcctgc	atgga	LAV BH10 BH8
atggatgaccctgagagagagtgttagagtggaggtttgacagccgcctagcatttcatcacgtggcccgag atggatgacccggagagagagtgttagagtggaggtttgacagccgcctagcatttcatcacatggcccgag atggatgaccctgagagagagtgttagagtggaggtttgacagccgcctagcatttcatcacatggcccgag	agctg	LAV BH10 BH8

catccggagtacttcaagaactgctga LAV catccggagtacttcaagaactgctga BH10 catccggagtacttcaagaactgctga BH8

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP



gacagggcttggaaaggattttgctataagatgggtggcaagtggtcaaaaaagtagtgtggttggatggcctactgta ARV  $\tt gacagggcttggaaaggcttttgctataagatgggtggcaagtggtcaaaacgtagtatgggtggatggtctata$ LAV agggaaagaatgagacgagctgagccagcagcaga tggggtgggagcagcatctcgagacctggaa ARV agggaaagaatgagacgagctgagccacgagctgagccagcagcagatggggtgggagcagtatctcgagacctggaa aaacatqqaqcaatcacaaqtaqcaatacaqcaqctaccaatqctqcttqtqcctqqctaqaaqcacaaqaqqaqqaq LAV aaacatqqaqcaatcacaaqtaqcaatacaqcagctactaatqctqattqtqcctqqctaqaaqcacaaqaqqaqqaa ARV LAV qaggtqggttttccagtcacacctcaggtacctttaagaccaatgacttacaaggcagctgtagatcttagccacttt  $\tt qaggtgggttttccagtcagacctcaggtacctttaagaccaatgacttacaaggcagctttagatattagccacttt$ ARV ttaaaagaaaaggggggactggaagggctaattcactcccaacgaagacaagatatccttgatctgtggatctaccac LAV ttaaaagaaaaggggggactggaagggctaatttggtcccaaagaagacaagagatccttgatctgtggatctaccacARV acacaaggctacttccctgattggcagaactacaccagggccaggggtcagatatccactgacctttggatggtgc LAV acacaaggctacttccctqattqqcaqaattacacaccaqqqccaqqqatcaqatatccactqacctttqqatqqtqc ARV  ${ t tacaagctagtaccagttgagccagataaggtagaagaggccaataaaggagagaacaccagcttgttacaccctgtg}-{ t LAV}$ ARV  $agcctgcatggaatggatgaccctgagagagagagtgttagagggtttgacagccgcctagcatttcatcacgtg \quad LAV \\$ agcctgcatgggatggaggacgcggagaaagaagtgttagtgtggaggtttgacagcaaactagcatttcatcacatg ARV gcccqaqaqctqcatccqqaqtacttcaaqaactqctqa LAV

qcccqaqaqctgcatccqqagtactacaaagactgctga ARV

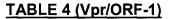
FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP

## TABLE 3 (Vpr/ORF-1)

tagcagaataggcgttactcaacagaggagagcaagaaatggagccagtagatcctag LAV tagcagaataggcgttactcgacagaggaggcaagaaatggagccagtagatcctag BH10 tagcagaataggcgttactcaacagaggaggaggaagaaatggagccagtagatcctag BH5

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP





 $\verb|atggaacaag| cccagaagggccacagagggagccatacaatgaatggacactagagcttttagaggagctt| ARV$ 

aagaatgaagctgttagacattttcctaggattttggctccatggcttagggcaacatatctatgaaacttatggggat LAV aagagagaagctgttagacattttcctaggccatggctccatagcttaggacaatatatctatgaaacttatggggat ARV

 $\verb|acttgggcaggagtggaagccata| at a a gaattctgcaaca actgctgtttatccatttcagaattgggtgtcgacat - LAV| \\$  $\verb|acttgggcaggagtggaagccata| at a a gaattctgcaaca actgctgttt attcatttcagaattgggtgtcaacat - ARV | ARV$ 

agcagaataggcgttactcaacagaggagagcaagaa atggagccagtagatcctag LAV agcagaataggcattattcaacagaggagagcaagaagaaatggagccagtagatcctaa ARV

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LL



gtagtacatgtaatgcaacctatacaaatag caatagcagcattagtagtagcaataataatagcaatagttgtg LAV gtagtacatgtaatgcaacctatacaaatag caatagtagcattagtagtagcaataataatagcaatagttgtg BH10 gtagtacatgtaacgcaacctataccaatagtaacaatagtagccttagcagtagcaataataatagcaatagttgtg BH8

tggtccatagtaatcatagaatataggaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaa LAV tggtccatagtaatcatagaatataggaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaa BH10 tggtccatagtaatcatagaatataggaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaa BH8

 $agag caga agacag t gg caat t gag ag t gaa gg agaa at at cag cact t gt gg agat gg gg t gg aaat gg gg cac cat \\ agag cagaag acag t gg caat t gag agaa at at cag cact t gt gg agat gg gg gt gg agat gg gg cac cat \\ agag cagaag acag t gg caat gag ag t gag agaa at at cag cact t gt gg ag at gg gg gt gg ag at gg gg cac cat \\ BH8$ 

gctccttgggatattgatgatctgtag LAV gctccttgggatgttgatgatctgtag BH10 gctccttgggatgttgatgatctgtag BH8

FINNEGAN HENDERSON FARABOW GARRETT& DUNNER LLP